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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/748,897 | 12/29/2003 | Anthony Joonkyoo Yun | PALO-002 | 7432 |

24353 7590 06/23/2010

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| EXAMINER | |
|---|---|
| RAMACHANDRAN, UMAMAHESWARI | |
| ART UNIT | PAPER NUMBER |
| 1627 | |

| MAIL DATE | DELIVERY MODE |
|---|---|
| 06/23/2010 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Advisory Action Before the Filing of an Appeal Brief | Application No. 10/748,897 | Applicant(s) YUN ET AL. | |
|---|---|---|---|
| | Examiner UMAMAHESWARI RAMACHANDRAN | Art Unit 1627 | |

***--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --***

THE REPLY FILED 07 June 2010 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☐ The period for reply expires _____months from the mailing date of the final rejection.
   b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: _____.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See notes below..
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

/SREENI PADMANABHAN/
Supervisory Patent Examiner, Art Unit 1627

Note: Applicants' arguments regarding the 102 rejection over Gambardella have been found to be persuasive and the rejection will be withdrawn. Applicants' arguments regarding the 112(1), 102 (Brevetti, Davies, Bugiardini, Shimizu) and 103 rejections have been fully considered and found not to be persuasive.

The 102 and 103 rejections are maintained for the reasons given in the final office action (Response to Arguments section). Applicants' claim treating a condition caused by an autonomic nervous system functionality administering a beta blocker (claim 1) and in addition non-beta blockers.

The claims are broad with respect to all the beta blockers, non beta blockers and the conditions (unrelated) to be treated.

112(1) rejection: The rejections are maintained for the reasons given in the final office action (Response to Arguments section) and for the reasons given below. Applicants argue that ample evidence exists in the literature and the drugs (beta blockers and non beta blockers) are well known agents and that optimization of dosages and management of side effects are routinely dealt with by physician and hence the claims are enabled and specification provide support for the invention even though examples are not provided by the Applicants. In response, it is not well known in the art that all the conditions claimed by the applicants' can be treated by every single beta blocker by itself or in combination with all the non-beta blockers claimed because there is literature such as Stockley (Are Beta blockers safe?, BMJ, 298, 10 Jun 1989) that teaches that two patients developed cardiac failure upon administration of nifedipine (a calcium channel blocker, one of the non beta blockers claimed in claim 24 of the instant application) along with propranolol or atelenol or alprenolol (p 1584, para 2). Again, providing or listing all of the compounds do not mean providing "blaze marks", direction, and/or guidance to one of skilled in the art so that one of skilled in the art can practice the full scope of the invention without undue experimentation. It will be an undue experimentation to a person of ordinary skill in the art to test whether the beta blockers are safe for all the conditions and in addition with all the numerous non-beta blockers claimed. Though the literature has taught the use of beta blockers or non-beta blockers by itself or in combination for certain conditions the scope of the claims are large with respect to the conditions and agents. It would require undue, unpredictable experimentation to practice the claimed invention of treating a subject for a condition caused by an autonomic nervous system abnormality comprising administering an effective amount of at least one beta-blocker to said subject to treat said subject for at least one of the conditions listed in claim 1 and to produce at least a portion of said subject's autonomic nervous system that is analogous to the parasympathetic activity/sympathetic activity ratio observed in a healthy 25 year old human subject.